UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
WESTERN DIVISION

CHRISTINA MARIE MCNALLY, Plaintiff, v. BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER PHARMA AG, and BAYER OY, Defendants.	Civil Action No._____3:15-cv-50059_____ **COMPLAINT AND JURY DEMAND**

Plaintiff CHRISTINA MARIE MCNALLY (referred to collectively as "Plaintiffs"), by and through their undersigned attorneys, hereby sue the Defendants, BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER PHARMA AG, and BAYER OY (hereinafter collectively referred to as "Defendants"), and alleges as follows:

BACKGROUND

1. This is an action for damages suffered by Plaintiff as a direct and proximate result of the Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of the Mirena intrauterine contraceptive system (hereinafter referred to as "Mirena" or "the subject product").

2. At all times material hereto, Mirena was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by the Defendants herein.

PARTIES AND JURISDICTION

3. Plaintiff CHRISTINA MARIE MCNALLY is a citizen and resident of the State of Illinois.

4. Upon information and belief, Defendants BAYER HEALTHCARE PHARMACEUTICALS INC. is, and at all relevant times, was a corporation organized under the laws of the State of Delaware, with its principal place of business in the State of New Jersey.

5. Upon information and belief, at all relevant times Defendants BAYER HEALTHCARE PHARMACEUTICALS INC. has transacted and conducted business in the State of Illinois and derived substantial revenue from interstate commerce.

6. Upon information and belief, at all relevant times, Defendants BAYER HEALTHCARE PHARMACEUTICALS INC. expected or should have expected that its acts would have consequences within the United States of America, and the State of Illinois in particular and derived substantial revenue from interstate commerce.

7. Upon information and belief, Defendants BAYER HEALTHCARE PHARMACEUTICALS INC. was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute Mirena as an intrauterine contraceptive system.

8. Defendants BAYER HEALTHCARE PHARMACEUTICALS, INC. is the holder of the approved New Drug Application ("NDA") for contraceptive device Mirena.

9. Upon information and belief, at all relevant times Defendant BAYER HEALTHCARE AG has transacted and conducted business in the State of New Jersey and derived substantial revenue from interstate commerce.

10. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE AG expected or should have expected that its acts would have consequences within the United States of America, and the State of New Jersey in particular and derived substantial revenue from interstate commerce.

11. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE AG exercises dominion and control over Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC.

12. Upon information and belief, Defendant BAYER PHARMA AG f/k/a BAYER SCHERING PHARMA AG is, and at all relevant times was, a global pharmaceutical corporation organized under the laws of Germany.

13. Upon information and belief, at all relevant times Defendant BAYER PHARMA AG f/k/a BAYER SCHERING PHARMA AG has transacted and conducted business in the State of New Jersey and derived substantial revenue from interstate commerce.

14. Upon information and belief, at all relevant times, Defendant BAYER PHARMA AG f/k/a BAYER SCHERING PHARMA AG expected or should have expected that its acts would have consequences within the United States of America, and the State of New Jersey in particular and derived substantial revenue from interstate commerce.

15. Upon information and belief, Defendant BAYER PHARMA AG f/k/a BAYER SCHERING PHARMA AG was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute Mirena® as an intrauterine contraceptive system.

16. Upon information and belief, effective July 1, 2011, BAYER SCHERING PHARMA AG was renamed BAYER PHARMA AG. BAYER PHARMA AG is the same corporate entity as BAYER SCHERING PHARMA AG.

17. Upon information and belief, Defendant BAYER OY is organized and exists under the laws of Finland and is headquartered at Pansiontie 47 20210 Turku, Finland.

18. Upon information and belief, Defendant BAYER OY is the current owner of the trademark relating to Mirena®.

19. Upon information and belief, at all relevant times, Defendant BAYER OY has transacted and conducted business in the State of New Jersey and derived substantial revenue from interstate commerce.

20. Upon information and belief, at all relevant times, Defendant BAYER OY expected or should have expected that its acts would have consequences within the United States of America, and the State of New Jersey in particular and derived substantial revenue from interstate commerce.

21. Defendants do business in Illinois through the sale of Mirena and other prescription drugs in the state.

22. At all times alleged herein, Defendants includes and included any and all parents, subsidiaries, affiliates, division, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

23. At all times relevant, Defendants was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, either directly or indirectly through third parties, subsidiaries or related entities, the contraceptive device, Mirena.

24. At all times relevant to this Complaint, each of the above Defendants conducted business and derived revenue in the State of Illinois, including through the prescription of Mirena to Plaintiff.

25. This court has personal jurisdiction over the Defendants in that the prescription drug at issue, Mirena, was prescribed to, marketed and sold to Plaintiff in the State of Illinois.

26. This court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between the parties and the amount in controversy exceeds $75,000.00 exclusive of interest and costs.

27. Venue in this district is appropriate under 28 U.S.C. § 1391 because a substantial part of the events giving rise to this claim occurred in this district, Plaintiff was prescribed, implanted with and used Mirena in this district, Plaintiffs suffered injuries in this district and because at all times relevant resided in this district.

28. Furthermore, the Defendants collectively have marketed, sold, distributed or otherwise distributed Mirena within the District of Illinois.

29. This suit is brought under common law of the State of Illinois to recover damages and other relief, including the costs of suit and reasonable attorneys' and expert fees, for the injuries the Plaintiffs have sustained as a result of the Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distributing, labeling, and/or sale of Mirena.

TAG-ALONG ACTION

30. This is a potential tag-along action and in accordance with 28 U.S.C. §14-7, it should be transferred to the United States District Court for the Southern District of New York for inclusion in *In re Mirena IUD Products Liability Litigation*, MDL 2434 (Hon. Cathy Seibel).

FACTUAL ALLEGATIONS

31. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

32. Mirena is an intrauterine contraceptive system made of flexible plastic that is inserted by a healthcare provider during an office visit.

33. The federal Food and Drug Administration (FDA) approved Defendants' New Drug Application for Mirena in December 2000. Today, more than 2 million of women in the United States use Mirena. It has been used by more the 15 million women worldwide.

34. The system releases levonorgestrel, a synthetic progestogen, directly into the uterus for birth control. Defendants admits "[i]t is not known exactly how Mirena works," but provides that Mirena may thicken cervical mucus, thin the uterine lining, inhibit sperm movement and reduce sperm survival to prevent pregnancy.

35. The Mirena intrauterine system (IUS) is designed to be placed within seven (7) days of the first day of menstruation and approved to remain in the uterus for up to five years. If continued use is desired after five years, the old system must be discarded and a new one inserted.

36. The package labeling recommends that Mirena be used in women who have had at least one child, suggesting that carrying a child to term may be complicated after Mirena use.

37. Mirena's label does not warn about spontaneous migration of the IUS, but only states that migration may occur if the uterus is perforated during insertion.

38. Defendants has failed to alter their product packaging to reflect the growing number of MedWatch Adverse Event reports related to embedment of and perforation through the uterine lining and/or migration of the IUD through the uterine lining after the period of insertion.

39. Defendants has a history of overstating the efficacy of Mirena while understating the potential safety concerns.

40. In or around March 2009, the Department of Health and Human Services' Division of Drug Marketing, Advertising, and Communications (DDMAC) issued a warning regarding Defendants' advertising materials for Mirena that constituted misbranding of the IUD in violation of the Federal Food, Drug and Cosmetic Act and FDA implementing regulations.

41. Specifically, DDMAC pointed out that Bayer failed to communicate any risk information, inadequately communicated Mirena's indications, and overstated the efficacy associated with the use of Mirena in Bayer-sponsored on internet search engines.

42. DDMAC requested that Bayer immediately cease the dissemination of the violative materials.

43. Then, in or around December 2009, Defendants was contacted by the Department of Health and Human Services' Division of Drug Marketing, Advertising, and Communications (DDMAC) regarding a consumer-directed program entitled "Mirena Simple Style Statements Program," a live presentation designed for "busy moms." The Simple Style program was presented in a consumer's home or other private setting by a representative from "Mom Central", a social networking internet site, and Ms. Barb Dehn, a nurse practitioner, in partnership with Defendants.

44. This Simple Style program represented that Mirena use would increase the level of intimacy, romance and emotional satisfaction between sexual partners. DDMAC determined these claims were unsubstantiated and, in fact, pointed out that Mirena's package insert states that at least 5% of clinical trial patients reported a decreased libido after use.

45. The Simple Style program script also intimated that Mirena use can help patients "look and feel great." Again, DDMAC noted these claims were unsubstantiated and that Mirena can cause a number of side effects, including weight gain, acne, and breast pain or tenderness.

46. The portion of the Simple Style script regarding risks omitted information about serious conditions, including susceptibility to infections and the possibility of miscarriage is a woman becomes pregnant on Mirena.

47. Finally, Defendants falsely claimed that Defendants' program falsely represented that the system required no compliance with a monthly routine.

48. As a result of Defendants' violation of the Federal Food, Drug, and Cosmetic Act and FDA's implementing regulations and ordered Bayer to cease use of the violative materials.

CASE-SPECIFIC ALLEGATIONS

49. Plaintiff CHRISTINA MARIE MCNALLY is 40 years old.

50. Plaintiff's physician George Stankevych, M.D., P.C., inserted the Mirena on or about February 28, 2008. Plaintiff tolerated the procedure well and neither Plaintiff nor her physician had any reason to suspect that the Mirena perforated her uterus.

51. On July 21, 2011, plaintiff presented to her physician for an annual physical. Upon examination, the Mirena IUD strings could not be seen. Plaintiff was scheduled for an ultrasound.

52. On August 3, 2011, Plaintiff underwent an ultrasound which confirmed that the Mirena IUD was in the proper location.

53. On March 6, 2013, Plaintiff presented to her provider for an annual exam and to have the Mirena IUD removed and replaced with a new one. The Mirena IUD was unable to be removed.

54. On March 18, 2013, Plaintiff presented for a hysteroscopic Mirena IUD removal. During the procedure, the Mirena IUD was not located and was believed to have perforated Plaintiff's uterus.

55. On May 6, 2013, Plaintiff underwent an abdominal x-ray which revealed that the Mirena IUD was in the left pelvis. Plaintiff was scheduled for laparoscopic removal.

56. On August 2, 2013, Plaintiff presented to Northern Illinois Medical Center and underwent a diagnostic laparoscopy. Plaintiff underwent adhesiolysis of pelvic adhesions and closure of a serosal abrasion of the large bowel, but the Mirena IUD was not located.

57. On November 4, 2013, Plaintiff presented to Northwestern Memorial Hospital and underwent a laparoscopic surgery to retrieve the Mirena IUD. The Mirena IUD was retrieved from the retroperitoneal space where an arm was seen protruding from the peritoneum.

58. As alleged herein, as a direct and proximate result of the Defendants' negligence and wrongful conduct, and the unreasonably dangerous and defective characteristics of the subject product, Plaintiff suffered severe and permanent physical injuries, and has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

FEDERAL REQUIREMENTS

59. Defendants had an obligation to comply with the law in the manufacture, design and sale of Mirena.

60. Upon information and belief, Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et. seq.*

61. With respect to Mirena, Defendants, upon information and belief, failed to comply with federal standards applicable to the sale of prescription drugs including but not limited to one or more of the following violations:

a. Mirena is adulterated pursuant to 21 U.S.C. § 351 because, among other things, it fails to meet established performance standards and/or the methods, facilities or controls used for its manufacture, packing, storage or installation is not in conformity with federal requirements.

b. Mirena is adulterated pursuant to 21 U.S.C. § 351 because, among other things, its strength differs from or its quality or purity falls below the standard set forth in the official compendium for Mirena and such deviations are not plainly stated on their labels.

c. Mirena is misbranded pursuant to 21 U.S.C. § 352 because, among other things, its labeling is false or misleading.

d. Mirena is misbranded pursuant to 21 U.S.C. § 352 because words, statements or other information required by or under authority of 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

e. Mirena is misbranded pursuant to 21 U.S.C. § 352 because the labeling does not bear adequate directions for use and/or the labeling does not bear adequate warnings against use where its use may be dangerous to health or against unsafe methods or duration of administration or application in such manner and form as are necessary for the protection of users.

f. Mirena is misbranded pursuant to U.S.C.§ 352 because it is dangerous to health when used in the manner, or with the frequency or duration prescribed, recommended or suggested in the labeling thereof.

g. Mirena does not contain adequate directions for use pursuant to 21 C.F.R. § 201.5 because, among other reasons of omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes or uses for which it is intended, including conditions, purposes or uses for which it is prescribed, recommended or suggested in their oral, written, printed or graphic advertising, and conditions, purposes or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application and/or (d) route or method of administration or application.

h. The Defendants violated 21 C.F.R. § 201.56 because the labeling was not informative and accurate.

i. Mirena is misbranded pursuant to 21 C.F.R. § 201.56 because the labeling was not updated and new information became available that caused the labeling to become inaccurate, false or misleading.

j. The Defendants violated 21 C.F.R. § 201.57 by failing to provide information that is important to the safe and effective use of the device including the potential of Mirena to migrate through the uterine lining or wall not related to insertion and the need for regular and/or consistent monitoring to ensure that the device has not migrated.

k. The Defendants violated 21 C.F.R. § 201.57 because they failed to identify specific tests needed for selection or monitoring of patients who used Mirena.

l. Mirena is mislabeled pursuant to 21 C.F.R.§ 201.57 because the labeling fails to describe serious adverse reactions and potential safety hazards, limitations in use imposed by it and steps that should be taken if they occur.

m. Mirena is mislabeled pursuant to 21 C.F.R. § 201.57 because the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the contraceptive device.

n. The Defendants violated 21 C.F.R. § 201.57 because the possibility that the device could migrate through the uterine lining and/or wall not associated with insertion is significantly more severe than the other reactions listed in the adverse reactions and yet the Defendants failed to list the risk of migration before the other adverse reactions on the labeling of Mirena.

o. Mirena violates 21 C.F.R. § 210.1 because the process by which it was manufactured, processed and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing or holding of a contraceptive device to assure that it meets the requirements as to safety and have the identity and strength and meets the quality and purity characteristic that they purport or are represented to possess.

p. Mirena violates 21 C.F.R. § 210.122 because the labeling and packaging materials do not meet the appropriate specifications.

q. Mirena violates 21 C.F.R. § 211.165 because the test methods employed by the Defendants are not accurate, sensitive, specific and/or reproducible and/or such accuracy, sensitivity, specificity and/or reproducibility of test methods have not been properly established and documented.

r. Mirena violates 21 C.F.R. § 211.165 in that it fails to meet established standards or specifications and any other relevant quality control criteria.

s. Mirena violates 21 C.F.R. § 211.198 because the written procedures describing the handling of all written and oral complaints were not followed.

t. Mirena violates 21 C.F.R. § 310.303 in that it is not safe and effective for its intended use.

u. The Defendants violated 21 C.F.R. § 310.303 because they failed to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA.

v. The Defendants violated 21 C.F.R. §310.305 and § 314.80 by failing to report adverse events associated with Mirena as soon as possible or at least within 15 days of the initial receipt by the Defendants of the adverse event report.

w. The Defendants violated 21 C.F.R. § 310.305 and § 314.80 by failing to conduct an investigation of each adverse event associated with Mirena evaluating the cause of the adverse event.

x. The Defendants violated 21 C.F.R. §310.305 and § 314.80 by failing to promptly investigate all serious, unexpected adverse experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA.

y. The Defendants violated 21 C.F.R. § 310.305 and § 314.80 by failing to keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse experiences.

z. The Defendants violated 21 C.F.R. § 310.305 and § 314.80 by failing to identify the reports they submitted properly such as by labeling them as "15-day Alert report" or "15-day Alert report follow-up."

aa. The Defendants violated 21 C.F.R. § 312.32 because they failed to review all information relevant to the safety of Mirena or otherwise received by the Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, commercial marketing experience, reports in the scientific literature and unpublished scientific papers as well as reports from foreign regulatory authorities that have not already been reported to the agency by the sponsor.

bb. The Defendants violated 21 C.F.R. § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse experience not already reported under the post-marketing 15-day alert report and/or (c) a

history of actions taken since the last report because of adverse experiences (for example labeling changes or studies initiated).

cc. The Defendants violated 21 C.F.R. § 314.80 by failing to submit a copy of a published article from scientific or medical journals along with one or more 15-day alert reports based on information from the scientific literature.

62. Defendants failed to meet the standard of care set by the above statutes and regulations which were intended for the benefit of individual consumers such as Plaintiffs making the Defendants liable.

COUNT I
PRODUCT LIABILITY – DEFECTIVE DESIGN

63. Plaintiffs repeat and incorporate by reference all other paragraphs of the Complaint as if fully set forth herein.

64. At all times material to this action, the Defendants was responsible for designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Mirena.

65. The subject product is defective and unreasonably dangerous to consumers.

66. Mirena is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation.

67. At all times material to this action, Mirena was expected to reach, and did reach, consumers in the State of Illinois, and throughout the United States, including Plaintiff herein, without substantial change in the condition in which it was sold.

68. At all times material to this action, Mirena was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and

unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, Mirena contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff to risks that exceeded the benefits of the subject product.

b. When placed in the stream of commerce, Mirena was defective in design and formulation, making the use of Mirena more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other contraceptives on the market for the prevention of pregnancy;

c. The subject product's design defects existed before it left the control of the Defendants;

d. Mirena was insufficiently tested;

e. Mirena caused harmful side effects that outweighed any potential utility; and

f. Mirena was not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Plaintiff herein, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiff.

69. In addition, at the time the subject product left the control of the Defendants, there were practical and feasible alternative designs, both in the form of the IUD and the drug emitted from the IUD, that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible, and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the product's utility.

70. As a direct and proximate result of the subject product's defective design, Plaintiff suffered severe and permanent physical injuries. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT II
PRODUCT LIABILITY – MANUFACTURING DEFECT

71. Plaintiffs repeat and incorporate by reference all other paragraphs of the Complaint as if fully set forth herein.

72. At all times material to this action, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Mirena.

73. At all times material to this action, Mirena was expected to reach, and did reach, consumers in the State of Illinois and throughout the United States, including Plaintiff herein without substantial change in the condition in which it was sold.

74. At all times material to this action, Mirena was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

g. When placed in the stream of commerce, Mirena contained manufacturing defects which rendered the product unreasonably dangerous;

h. The subject product's manufacturing defects occurred while the product was in the possession and control of the Defendants;

i. The subject product was not made in accordance with the Defendants' specifications or performance standards; and

j. The subject product's manufacturing defects existed before it left the control of the Defendants.

75. As a direct and proximate result of the subject product's manufacturing defects, Plaintiff suffered severe and permanent physical injuries. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT III
PRODUCT LIABILITY - FAILURE TO WARN

76. Plaintiffs repeat and incorporate by reference all other paragraphs of the Complaint as if fully set forth herein.

77. Mirena is a defective and therefore unreasonably dangerous product, because its labeling fails to adequately warn consumers and prescribers of, among other things, the risk of migration of the product post-insertion, development of endometriosis resulting from uterine perforation, or possibility that device complication may necessitate hysterectomy.

78. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the pharmaceutical, Mirena, and in the course of same, directly advertised or marketed the product to consumers or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of Mirena.

79. Mirena was under the exclusive control of Defendants and was unaccompanied by appropriate warnings regarding all of the risks associated with its use. The warnings given did not accurately reflect the risk, incidence, symptoms, scope or severity of such injuries to the consumer or physicians. The promotional activities of Defendants further diluted or minimized the warnings given with the product.

80. Defendants downplayed the serious and dangerous side effects of Mirena to encourage sales of the product; consequently, Defendants placed its profits above its customers' safety.

81. Mirena was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert Plaintiff to the dangerous risks and reactions associated with it. Even though Defendants knew or should have known of the risks and reactions associated with Mirena, they still failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.

82. Plaintiff used Mirena as intended and as indicated by the package labeling or in a reasonably foreseeable manner.

83. Plaintiff could not have discovered any defect in Mirena through the exercise of reasonable care.

84. Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field and, further, Defendants had knowledge of the dangerous risks and side effects of Mirena.

85. Plaintiff did not have the same knowledge as Defendants and no adequate warning was communicated to her physician(s).

86. Defendants had a continuing duty to warn consumers, including Plaintiff and her physicians, and the medical community of the dangers associated with Mirena, and by negligently and/or wantonly failing to adequately warn of the dangers associated with its use, Defendants breached their duty.

87. Although Defendants knew, or were reckless in not knowing, of the defective nature of Mirena, they continued to design, manufacture, market, and sell Mirena without providing adequate warnings and instructions concerning the use of Mirena so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by Mirena.

88. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiff suffered profound injuries, required and continues to require medical treatment, and incurred and continues to incur medical and hospital expenses.

89. As a direct and proximate result of the subject product's defective and inappropriate warnings, Plaintiff suffered severe and permanent physical injuries. Plaintiff has endured

substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT IV
PRODUCT LIABILITY – BREACH OF IMPLIED WARRANTY

90. Plaintiffs repeat and incorporate by reference all other paragraphs of the Complaint as if fully set forth herein.

91. The Defendants designed, manufactured, marketed, distributed, supplied and sold the subject product for the prevention of pregnancy.

92. At the time that the Defendants manufactured, marketed, distributed, supplied, and/or sold Mirena, they knew of the use for which the subject product was intended and impliedly warranted it to be of merchantable quality and safe and fit for such use.

93. Plaintiff, individually and through her prescribing physician, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

94. Plaintiff was prescribed, purchased, and used the subject product for its intended purpose.

95. Due to the Defendants' wrongful conduct as alleged herein, Plaintiff could not have known about the nature of the risks and side effects associated with the subject product until after she used it.

96. Contrary to the implied warranty for the subject product, Mirena was not of merchantable quality, and was not safe or fit for its intended uses and purposes, as alleged herein.

97. As a direct and proximate result of the Defendants' breach of implied warranty under Ill. Comp. Stat. Ann. Ch. 810, 5/2-314, *et seq* and Illinois common law, Plaintiff suffered severe and permanent physical injuries. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT V
PRODUCT LIABILITY – NEGLIGENCE

98. Plaintiffs repeat and incorporate by reference all other paragraphs of the Complaint as if fully set forth herein.

99. At all times material hereto, the Defendants had a duty to exercise reasonable care to consumers, including Plaintiff herein, in the design, development, manufacture, testing, inspection, packaging, promotion, marketing, distribution, labeling, and/or sale of Mirena.

100. The Defendants breached their duty of reasonable care to Plaintiffs in that they negligently designed, developed, manufactured, tested, inspected, packaged, promoted, marketed, distributed, labeled, and/or sold the subject product.

101. Plaintiff's injuries and damages alleged herein were and are the direct and proximate result of the carelessness and negligence of the Defendants as follows:

k. In its design, development, research, manufacture, testing, packaging, promotion, marketing, sale and/or distribution of the subject product;

l. In its failure to warn or instruct, and/or adequately warn or adequately instruct, users of the subject product, including Plaintiff herein, of said product's dangerous and defective characteristics;

m. In its design, development, implementation, administration, supervision and/or monitoring of clinical trials for the subject product;

n. In its promotion of the subject product in an overly aggressive, deceitful and fraudulent manner, despite evidence as to the product's defective and dangerous characteristics due to its propensity to cause serious injury and/or death;

o. In representing that the subject product was safe for its intended use when, in fact, the product was unsafe for its intended use;

p. In failing to perform appropriate pre-market testing of the subject product;

q. In failing to perform appropriate post-market testing of the subject product; and

r. In failing to perform appropriate post-market surveillance of the subject product.

102. The Defendants knew or should have known that consumers such as Plaintiff herein would foreseeably suffer injury as a result of the Defendants' failure to exercise reasonable and ordinary care.

103. As a direct and proximate result of Defendants' carelessness and negligence, Plaintiff suffered severe and permanent physical injuries. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will

continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VI
BREACH OF EXPRESS WARRANTY

104. Plaintiffs repeat and incorporate by reference all other paragraphs of the Complaint as if fully set forth herein.

105. Defendants expressly warranted that Mirena was safe and fit for use by consumers and users including Plaintiff for its intended purpose, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested and fit for its intended use.

106. At the time of the making of the express warranties, Defendants knew or should have known of the purpose for which Mirena was to be used and warranted the same to be, in all respects, fit, safe, and effective and proper for such purpose.

107. At the time of the making of the express warranties, Defendants knew or should have known that, in fact, said representations and warranties were false, misleading, and untrue in that Mirena was not safe and fit for its intended use and, in fact, produces serious injuries to the user.

108. Members of the medical community, including, but not limited to, Plaintiff's physicians, reasonably relied upon the skill and judgment of Defendants, and upon said express warranties, in prescribing, recommending and/or dispensing Mirena.

109. Plaintiff relied on the Defendants' express warranties.

110. Defendants breached said express warranties under Ill. Comp. Stat. Ann. Ch. 810, 5/2-313 *et seq.*, in that Mirena was not safe and fit for its intended use and, in fact, causes debilitating and potentially lethal side effects with greater frequency than safer alternative methods of birth control.

111. As a direct and proximate result of the Defendants' breach of express warranty, Plaintiff suffered severe and permanent physical injuries. Plaintiff has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VII
VIOLATION OF THE ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT

112. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein and further alleges as follows:

113. At all times relevant, the Illinois Consumer Fraud & Deceptive Practices Act, 815 ILCS 505/1 et seq., (hereinafter "the Act") prohibits "the use of any deception, fraud, false pretense, false promise, misrepresentation or concealment, suppression or omission of any material fact … in the conduct of any trade or commerce" and declares such acts or practices as unlawful.

114. Defendants violated the Act by the use of false and misleading misrepresentations or omissions of material fact in connection with the marketing, promotion, and sale of Mirena.

115. Defendants communicated the purported benefits of Mirena while failing to disclose the serious and dangerous side effects related to the use of Mirena with the intent that customers, like Plaintiff, and her healthcare providers would rely upon the misrepresentations and purchase or prescribe Mirena.

116. As a result of violating the Act, Defendants caused Plaintiff to be prescribed and to use Mirena, causing injuries as described herein. As a result, Plaintiff suffered harm, economic loss, non-economic loss and damages for aggravating circumstances and other losses in an amount to be proven at trial.

WHEREFORE Plaintiff demands judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, treble damages, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

COUNT VIII
PUNITIVE DAMAGES

117. Plaintiffs repeat and incorporate by reference all other paragraphs of the Complaint as if fully set forth herein.

118. At all times material hereto, the Defendants knew or should have known that the subject product was inherently more dangerous than alternative methods of birth control.

119. At all times material hereto, the Defendants attempted to misrepresent and did misrepresent facts concerning the safety of the subject product.

120. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff herein, concerning the safety of the subject product.

121. At all times material hereto, the Defendants knew and recklessly disregarded the fact that Mirena causes debilitating and potentially lethal side effects with greater frequency than safer alternative methods of birth control.

122. Notwithstanding the foregoing, the Defendants continued to aggressively market the subject product to consumers, including Plaintiff herein, without disclosing the aforesaid side effects when there were safer alternative methods of birth control.

123. The Defendants knew of the subject product's defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff herein, in conscious and/or negligent disregard of the foreseeable harm caused by Mirena.

124. Defendants intentionally concealed and/or recklessly failed to disclose to the public, including Plaintiff herein, the potentially life threatening side effects of Mirena in order to ensure continued and increased sales.

125. The Defendants' intentional and/or reckless failure to disclose information deprived Plaintiffs of necessary information to enable her to weigh the true risks of using the subject product against its benefits.

126. As a direct and proximate result of the Defendants' conscious and deliberate disregard for the rights and safety of consumers such as the Plaintiff, Plaintiff suffered severe and permanent physical injuries. Plaintiff has endured substantial pain and suffering. She has incurred

significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. Plaintiff's injuries and damages are permanent and will continue into the future.

127. The aforesaid conduct of Defendants was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including Plaintiff herein, thereby entitling the Plaintiffs to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against each of the Defendants as follows:

a. Awarding actual damages to the Plaintiff incidental to Plaintiff's purchase and use of Mirena in an amount to be determined at trial;

b. Awarding treble and/or punitive damages to the Plaintiff;

c. Awarding pre-judgment and post-judgment interest to the Plaintiff;

d. Awarding the costs and the expenses of this litigation to the Plaintiff;

e. Awarding reasonable attorneys' fees and costs to the Plaintiff as provided by law; and

f. Granting all such other relief as the Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

The Plaintiff hereby demands a trial by jury on all Counts and as to all issues.

Dated: March 6, 2015

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